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Display Date 1-24-03

Publication Date 1-27-03

Certifier G Pressley

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration 0360 '03 JAN 24 A5:28

[Docket No. 02P–0068]

Determination That Chymopapain 10,000 Units/Vial Injection Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that CHYMODIACTIN (chymopapain 10,000 units/vial injection) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for chymopapain 10,000 units/vial injection.

FOR FURTHER INFORMATION CONTACT: Brian L. Pendleton, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drugs approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA.

The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

CHYMODIACTIN (chymopapain 10,000 units/vial injection) is the subject of NDA 18–663. CHYMODIACTIN is indicated for the treatment of patients with documented herniated lumbar intervertebral discs whose symptoms and signs, particularly sciatica, have not responded to an adequate period or periods of conservative therapy. FDA approved the NDA for CHYMODIACTIN on November 10, 1982.

On February 12, 2002, ChymoCorp submitted a citizen petition (Docket No. 02P–0068/CP1) under 21 CFR 10.30 requesting that the agency determine whether chymopapain manufactured by Abbott Laboratories under the brand name CHYMODIACTIN was withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that CHYMODIACTIN (chymopapain 10,000 units/vial injection) was not withdrawn from sale for reasons of safety or effectiveness. Abbott Laboratories informed the agency by telephone that the company no longer markets CHYMODIACTIN. FDA has independently evaluated relevant literature and data for possible postmarketing adverse event reports, but has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined previously, CHYMODIACTIN (chymopapain 10,000 units/vial injection) was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list chymopapain 10,000 units/vial injection in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to CHYMODIACTIN (chymopapain 10,000 units/vial injection) may be approved by the agency.

Dated: 1/15/03

January 15, 2003.

Margaret M. Dotzel,
Assistant Commissioner for Policy.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

BILLING CODE 4160–01–S